

PUBLIC PROTECTION CABINET
Department of Insurance
Division of Health and Life Insurance and Managed Care
(Amendment)

806 KAR 17:575. Pharmacy benefit managers.

RELATES TO: KRS 304.1-050, 304.2-160, 304.2-165, 304.9-020, 304.17A-161, 304.17A-162

STATUTORY AUTHORITY: KRS 304.2-110, 304.2-160, 304.2-165, 304.9-020, 304.17A-161, 304.17A-162

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes ~~[provides that]~~ the commissioner to promulgate ~~[may make]~~ reasonable administrative regulations necessary for, or as an aid to, the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. KRS 304.17A-162 requires the department to promulgate an administrative regulation ~~[regulations]~~ to establish ~~[establishing]~~ the manner in which a pharmacy benefit manager shall respond to an appeal regarding maximum allowable cost pricing, the manner in which a pharmacy benefit manager shall make available the sources for drug pricing data to contracted pharmacies ~~[makes available to contracted pharmacies information regarding sources for drug price data]~~, a comprehensive list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug, and weekly list updates ~~[updates to the list]~~. KRS 304.2-160, 304.2-165, 304.9-020, 304.17A-161, and 304.17A-162 together authorize the department to promulgate an administrative ~~[provide authority for the department's]~~ regulation to establish the specific listing requirements and appeal processes related to maximum allowable cost pricing for pharmacy benefit managers ~~[of pharmacy benefit managers and the specific maximum allowable cost pricing and appeal process set forth in this administrative regulation]~~. This administrative regulation establishes ~~[the process for a pharmacy benefit manager's maximum allowable cost appeals process,]~~ the process for the department's review of a complaint associated with a maximum allowable cost appeal~~;~~ and the requirements for the cost listings made available by a pharmacy benefit manager.

Section 1. Definitions. (1) "Contracted pharmacy" or "pharmacy" is defined by KRS 304.17A-161(1).

(2) "Department" is defined by KRS 304.1-050(2).

(3) "Maximum Allowable Cost" is defined by KRS 304.17A-161(3).

(4) "Pharmacy Benefit Manager" is defined by KRS 304.17A-161(4).

Section 2. Maximum Allowable Cost Pricing Appeal Process.

(1) A pharmacy benefit manager shall establish a maximum allowable cost pricing appeal process where a contracted pharmacy or the pharmacy's designee may appeal if:

(a) The maximum allowable cost established for a drug reimbursement is below the cost at which the drug is available for purchase by pharmacists and pharmacies in Kentucky from national or regional wholesalers licensed in Kentucky by the Kentucky Board of Pharmacy; or

(b) The pharmacy benefit manager has placed a drug on the maximum allowable cost list in violation of KRS 304.17A-162(8).

(2) The pharmacy benefit manager shall accept an appeal submitted by a contracted pharmacy on or before sixty (60) days of the initial claim and the pharmacy benefit manager's appeal process shall include the following:

~~(a) The pharmacy benefit manager shall accept an appeal by a contracted pharmacy on or before sixty (60) days of the initial claim];~~

~~(a) [(b)]~~ Notification to the appealing party that the appeal has been received, and the names, addresses, email addresses, and telephone numbers of the pharmacy benefit manager's contact persons for questions regarding the maximum allowable cost appeal process; and

~~(b) [(c)]~~ A provision allowing a contracted pharmacy, pharmacy service administration organization, or group purchasing organization, to initiate the appeal process, regardless if an appeal has previously been submitted by a pharmacy or the pharmacy's designee outside of Kentucky, by contacting the pharmacy benefit manager's designated contact person electronically, by mail, or telephone. If the appeal process is initiated by telephone, the appealing party shall follow up with a written request within three (3) days.

(3) The pharmacy benefit manager's maximum allowable cost pricing appeal process shall be readily accessible to contracted pharmacies electronically, through publication on the pharmacy benefit manager's website, and in either the contracted pharmacy's contract with the pharmacy benefit manager or through a pharmacy provider manual distributed to contracted pharmacies, pharmacy service administration organizations, and group purchasing organizations.

(4) For an appeal received from a pharmacy services administration organization or a group purchasing organization related to a dispute regarding maximum allowable cost pricing, a pharmacy benefit manager may request documentation that the pharmacy services administration organization or group purchasing organization is acting on behalf of a contracted pharmacy before responding to the appeal.

(5) The pharmacy benefit manager shall investigate, resolve, and respond to the appeal within ten (10) calendar days of receipt of the appeal. Upon resolution, the pharmacy benefit manager shall issue a written response to the appealing party that shall include the following:

(a) The date of the decision;

(b) The name, phone number, mailing address, email address, and title of the person making the decision; and

(c) A statement setting forth the specific reason for the decision, including:

1. If the appeal is granted:

a. The amount of the adjustment to be paid retroactive to the initial date of service to the appealing pharmacy;

b. The drug name, national drug code, and prescription number of the appealed drug; and

c. The appeal number assigned by the pharmacy benefit manager, if applicable; or

2. If the appeal is denied:

a. The national drug code of the appealed drug, or the national drug code of a therapeutically equivalent drug as referenced [defined] in KRS 304.17A-162(9), of the same dosage, dosage form, and strength of the appealed drug; and

b. The Kentucky licensed wholesaler offering the drug at or below maximum allowable cost on the date of fill.

(6) When a pharmacy benefit manager grants an appeal for which a price update is warranted in accordance with KRS 304.17A-162(2), the pharmacy benefit manager shall individually notify contracted pharmacies of the date of the granted appeal, the appealed drug, initial date of service, national drug code, generic code number, applicable information to identify the health benefit plan, and retroactive price update by the time of release of the next scheduled maximum allowable cost update following the appeal decision by:

(a) Mail Courier;

(b) Electronic mail;

(c) Facsimile; or

(d) Web portal posting for sixty (60) days and corresponding electronic communication to a contracted pharmacy with hyperlink to the portal for the granted appeal. A pharmacy benefit manager shall include in the beginning and upon renewal of the contract with a pharmacy or the pharmacy's representative, notice~~[-]~~ and instructions for how to access and use the web portal.

(7) All contracted pharmacies permitted to reverse and resubmit claims following a granted appeal pursuant to KRS 304.17A-162(2) shall submit claims to the pharmacy benefit manager within sixty (60) days of notification that the appeal was granted.

(8) A pharmacy benefit manager shall submit the maximum allowable cost pricing appeal process and a template response satisfying the requirements of subsection (5) of this section to the department for review and approval.

Section 3. Department Review of Maximum Allowable Cost Pricing Appeal. (1) A contracted pharmacy or the pharmacy's designee may file a complaint with the department following a final decision of the pharmacy benefit manager, ~~[to the department]~~ in accordance with KRS 304.2-160 and 304.2-165.

(2) A complaint shall be submitted to the department no later than thirty (30) calendar days from the date of the pharmacy benefit manager's final decision.

(3) The department shall be entitled to request additional information necessary to resolve a complaint from any party in accordance with KRS 304.2-165 and 304.17A-162(5).

Section 4. Maximum allowable cost list availability and format. (1) The pharmacy benefit manager shall make available to the contracted pharmacy a comprehensive list of drugs subject to maximum allowable cost pricing.

(2) The comprehensive maximum allowable cost pricing list shall:

(a) Be a complete listing by drug in an electronically accessible format ~~[, unless, upon a pharmacy's written request the list be provided in a paper or other agreed format within two (2) business days upon receiving the necessary information required for each list requested;]~~

(b) Identify the applicable health plan for which the pricing is applicable;

(c) ~~[Be electronically searchable and sortable]~~ Contain the ability to search and sort drugs electronically by individual drug name, national drug code, and generic code number;

(d) Contain data elements including the drug name, national drug code, per unit price, and strength of drug;

(e) List a specific maximum allowable cost for each drug that will be reimbursed by the pharmacy benefit manager;

(f) Provide the effective date for that maximum allowable cost price; and

(g) Provide the date the maximum allowable cost list was updated.

(3) The pharmacy benefit manager shall retain, in accordance with subsection (2)(a) of this section, historical pricing data for a minimum of 120 days.

Section 5. Weekly Updates to Maximum Allowable Cost Price List.

(1) Pharmacy benefit managers shall send to all contracted pharmacies one (1) weekly update to the maximum allowable cost price list.

(2) The weekly update shall include the information below for all drugs added, removed, or changed in price since the last weekly update:

(a) Be in an electronically accessible format on the pharmacy benefit manager's Web site; ~~unless, upon written request by the pharmacy the update be provided in paper or other agreed format within two (2) business days of receipt of the request from the contracted pharmacy];~~

(b) Identify the basis for each drug's inclusion on the update;

- (c) If a drug is added to the maximum allowable cost list, the maximum allowable cost price shall be indicated;
- (d) Identify all drugs removed from the maximum allowable cost list;
- (e) If a change in the maximum allowable cost price is made, include the old price, and new price;
- (f) Identify the drug name, national drug code, generic code number, and the applicable health benefit plan information; and
- (g) Identify the effective date of the change.

Section 6. Data Source Availability. Each pharmacy benefit manager shall identify electronically or within contracts to all contracted pharmacies the national drug pricing compendia, or sources used to obtain drug price data for those drugs, subject to maximum allowable cost provisions. If any changes are made to the data sources following the execution of a contract, the pharmacy benefit manager shall individually notify the contracted pharmacies of the changes [either] through correspondence submitted electronically, by facsimile, or by mail courier.

Section 7. Annual report. All pharmacy benefit managers licensed to do business in Kentucky shall transmit ~~[at least annually by March 31 to the department]~~ a Pharmacy Benefit Manager Annual Report to the department at least annually, by March 31 of each year.

Section 8. Incorporation by Reference. (1) "Pharmacy Benefit Manager Annual Report," 06, 2017 [June 2017], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, The Mayo-Underwood Building, 500 Mero Street [215 West Main Street], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

SHARON P. CLARK, Commissioner

RAY A. PERRY, Secretary

APPROVED BY AGENCY: November 5, 2021

FILED WITH LRC: November 12, 2021 at 9:58 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 a.m. on January 21, 2021 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 p.m. on January 31, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: Abigail Gall, Regulations Coordinator, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email abigail.gall@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Abigail Gall

(1) Provide a brief summary of:

(a) What this administrative regulation does: The administrative regulation expounds upon the Department of Insurance's oversight of the relationship between a pharmacy and pharmacy benefit manager as directed by KRS 304.17A-162. This administrative regulation provides further detail on the required internal and external complaint processes for pharmacy benefit managers. These appeals are available to pharmacists contesting the amount of a pharmacy benefit manager's maximum allowable cost payments received for prescriptions. The regulation sufficiently narrows the scope of the Department's review in the appeal process to ensure the pharmacy benefit manager has applied the appropriate standards required pursuant to KRS 304.17A-162. This administrative regulation requires a pharmacy benefit manager to provide the Department annual reports to allow for the identification of any issues in this specific process and determine any necessary Department action.

(b) The necessity of this administrative regulation: The administrative regulation is necessary to implement KRS 304.17A-162.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.17A-162 requires the Department to promulgate administrative regulations concerning specific aspects of the relationship between a pharmacy and a pharmacy benefit manager.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The administrative regulation clarifies the scope of the Department's review of maximum allowable cost prescription appeals. It also provides a reporting obligation on behalf of pharmacy benefit managers to allow the Department to efficiently oversee pharmacy benefit managers and identify any areas of concern.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation address drafting requirement, as well as require all information be available electronically.

(b) The necessity of the amendment to this administrative regulation: In reviewing applications for Pharmacy Benefit Managers, the Department has addressed common questions, particularity related to the electronic format of the maximum allowable cost list and its searchability, so the amendments address the concerns raised.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.17A-162 requires the Department to promulgate administrative regulations concerning specific aspects of the relationship between a pharmacy and a pharmacy benefit manager. The amendments to this regulation clarify the beforementioned relationship, and the processes affiliated with them.

(d) How the amendment will assist in the effective administration of the statutes: Three amendments clarify the regulation's intent, and require information to be available electronically which addresses many concerns that have been brought to the Department's attention.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Pharmacies, pharmacy benefit managers, and insurers operating within the Commonwealth of Kentucky will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The requirements imposed

upon each of the entities are similar to existing requirements already found in other states. To comply with these Kentucky specific provisions, the pharmacy benefit managers will need to configure their operating systems in such a manner to allow pharmacies sufficient access to their maximum allowable cost price lists and weekly updates with the required information electronically. Pharmacy benefit managers will be required to maintain appeal data used in generating the annual reports.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The requirements established in this regulation are very similar to requirements already established in other states. The cost of compliance is minimal.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The parties will benefit from greater transparency in the prescription pricing process and the adoption of an official appeal process, with Department oversight, that will prevent parties from taking advantage of each other's position.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This should not cost the Department as this is a current process included in the current budget.

(b) On a continuing basis: The Consumer Protection Division will continue to handle complaints submitted, and should have no increase of cost on the Department.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The current operational budget of the Department.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There is no anticipated increase of fees.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not used as the regulation applies to all entities operating as pharmacy benefit managers.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Kentucky Department of Insurance.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.17A-162.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue for state or local government.

(c) How much will it cost to administer this program for the first year? The Department does not anticipate any additional cost.

(d) How much will it cost to administer this program for subsequent years? The Department anticipates the current personnel in the Department of Insurance will continue to investigate complaints.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): .

Expenditures (+/-):

Other Explanation: